

LLOYD BELL, Individually and
 As Executor of the Estate of BETTY
 WHITLEY BELL, Deceased,

 Plaintiff,

 v.

 AMERICAN INTERNATIONAL
 INDUSTRIES, INC., et al.,

 Defendants.

V.)
)
AMERICAN INTERNATIONAL)
INDUSTRIES, INC., et al.,)
)
Defendants.)

Plaintiff files this Response to Defendant American International Industries’ (“AII”) Motion to Vacate the Preliminary Protective Order of September 25, 2020, and Whittaker, Clark & Daniels, Inc.’s (“WCD”) Notice of Joinder¹ therein, and shows the Court as follows:

Plaintiff retained Dr. Jacqueline Moline, an expert in occupational medicine. (Dkt. 179-1.) Dr. Moline, along with Kristin Bevilacqua, Maya Alexandri, and Ronald Gordon, authored a peer-reviewed article entitled “Mesothelioma Associated with the Use of Cosmetic Talc,” published in the Journal of Occupational and Environmental Medicine in January 2020 (“Moline Study” or “Study”). (Dkt. 274-1.) The Study examined data for 33 anonymous human subjects with

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malignant mesothelioma and no known asbestos exposure other than cosmetic talcum powder. The Study provides evidence of the link between mesothelioma and exposure to cosmetic talc.

AII suspected that Betty Bell, decedent, was one of the human subjects in the Moline Study. AII subpoenaed documents from Dr. Moline's employer, Northwell Health, Inc. ("Northwell"). Though not responsive to the subpoena (or the HIPAA authorization AII also provided to Northwell) and despite Plaintiff's motion to quash, Northwell produced one document ("the Northwell document"), which confirmed that Mrs. Bell was one of human subjects. Plaintiff filed an emergency motion for protective order to protect the confidentiality of the identities of the human subjects. On September 25, 2020, Magistrate Judge Peake entered a protective order, prohibiting disclosure of information outside of this case regarding Mrs. Bell's identity as one of the 33 study subjects. (Dkt. 206, 9/25/20 Hearing Transcript, at 94:19-24, 96:6-12.) Thereafter, the Court granted summary judgment in favor of AII on the issue of successor liability, and the remaining Defendants were dismissed. Final judgment was entered on August 25, 2021; the case is closed.

Defendants now seek to vacate the protective order so that they can disclose Mrs. Bell's identity as one the human subjects in the Moline Study in other cases. Defendants' entire motion focuses on the Study's characterization of Mrs. Bell as having no known asbestos exposure apart from her exposure to cosmetic talc because Plaintiff and Mrs. Bell filed workers' compensation claims, which were denied and dismissed. Despite the absence of any actual evidence that Mrs. Bell was exposed to asbestos at her jobsites, Defendants assert that if her identity as one of the 33 subjects of the Moline Study continues to be protected, Dr. Moline and plaintiffs' counsel will be "free to mislead the courts and fact finders across the nation with the false claim that none of the 33 cases involved alleged exposures to asbestos other than contaminated cosmetic talc." (Dkt. 369,

at 25.) Defendants are not prevented from effectively cross-examining Dr. Moline on the Study or the methodology employed. Defendants' accusations of fraud and misrepresentation lobbed at Dr. Moline are baseless and unfounded and provide no support for the lifting of the protective order.

Defendants bear the burden to show good cause exists to modify or vacate the protective order, but have failed to meet their burden. The de-anonymization of Mrs. Bell as a study subject would not help Defendants discredit the Moline Study—there is no evidence that Mrs. Bell had any known alternate exposures. Moreover, Defendants did not file a motion pursuant to Local Rule 5.4(e) to unseal any court records, but cited related authority. Regardless, Defendants have failed to show that sealing is no longer needed. The filings are not judicial records subject to the public right of access, but, even if they were, the confidentiality interests involved in human-subjects research outweigh any interest of the public in disclosure.

BACKGROUND

Betty Bell and her husband, Lloyd Bell (“Plaintiff”), originally filed suit in New Jersey in November 2015, asserting claims against AII, Brenntag North American, Inc., Brenntag Specialties, Inc., Colgate-Palmolive Company, Cyprus Amax Minerals Company, Metropolitan Life Insurance Company, and Whittaker Clark & Daniels, Inc. that exposure to asbestos in talc supplied by or incorporated into talcum powder products manufactured by Defendants caused Mrs. Bell’s mesothelioma. The parties participated in discovery, including written discovery and the deposition of Mrs. Bell, before the case was dismissed based on forum non conveniens on December 22, 2016. Mr. and Mrs. Bell then filed this case on February 8, 2017, asserting claims against the same defendants (except Metropolitan Life Insurance Company). (Dkt. 1.) Mrs. Bell

passed away as a result of her mesothelioma on June 3, 2017. Plaintiff filed an amended complaint asserting a wrongful death on October 23, 2017. (Dkt. 39-2, 44.)

A. Workers' Compensation Claims

Mrs. Bell filed workers' compensation claims against two former employers, Hoechst Celanese Corporation ("Celanese") and Pillowtex Corporation f/k/a Fieldcrest Cannon, Inc. f/k/a Cannon Mills ("Pillowtex"), both of which appear on bankruptcy trust jobsite lists. Based on his knowledge and experience gained from representing prior claimants that had worked at the same jobsites, Plaintiff's counsel, Mr. William Graham of Wallace and Graham, P.A., had a good faith basis for filing the claims. (Dkt. 162, at 67:23-68:10, 70:18-71:2.) However, there is no evidence that Mrs. Bell was *actually* exposed to asbestos at either jobsite. (*Id.* at 75:11-17.)

Mrs. Bell's and Plaintiff's workers' compensation claims are detailed in Plaintiff's Response to AII's Motion to Admit Workers' Compensation Claims as Statements Against an Opposing Party. (*See* Dkt. 333, at 3-6.) Both claims were filed without description of Mrs. Bell's exposures to asbestos while working. (Dkt. 322-2, 322-3; Dkt. 322-5, 322-6.)² The claims were denied and dismissed. (Dkt. 333-1, 333-2, 333-3; Dkt. 333-4, 333-5, 333-6, 333-9, 333-10, 333-11.)

On June 21, 2016, Mrs. Bell was deposed in the New Jersey case and was questioned regarding her workers' compensation claims. (Dkt. 333-12.) She testified that she had filed the workers' compensation claims but that she did not know if she was actually exposed as asbestos at Cannon Mills (Pillowtex) or Celanese as asbestos was not discussed. (*Id.* at 514:16-515:1, 527:24-528:8, 530:11-532:5.)

² The workers' compensation claims were disclosed both in Mrs. Bell's deposition and in discovery responses served in the New Jersey case in 2015.

B. The Moline Study

In 2019, Dr. Moline co-authored the peer-reviewed Moline Study, titled “Mesothelioma Associated With the Use of Cosmetic Talc.”³ (Dkt. 274-1; *see also* Dkt. 265-1.) The Study is a case series study of 33 anonymous individuals with malignant mesothelioma that were referred to Dr. Moline for medico-legal evaluation. (Dkt. 274-1, at 11.) Prior to drafting the Study, Dr. Moline sought and secured approval from Northwell’s Human Research Protection Program through its Institutional Review Board (“IRB”). (Dkt. 265-1, Moline Affidavit, at 2.) The Northwell IRB is an independent research ethics review board—mandated by law and applicable regulations. (*Id.*) It consists of healthcare professionals, scientists, and local community members and serves to protect research participants’ privacy and confidentiality rights. (*Id.*) Based on Dr. Moline’s representations regarding the anonymization of her study subjects and provisions to protect and maintain the confidentiality of data and participants, Northwell’s IRB granted approval on March 23, 2018, stating that the study met the criteria outlined in 45 C.F.R. § 46.110 and 21 C.F.R. § 56.110. (*Id.* at 3.)

Data for the 33 anonymous subjects was gathered from medical records and deposition transcripts: “[e]xposure data was obtained from sworn testimony by the [subjects], which included extensive questioning regarding all sources of asbestos exposure.” (*Id.*) In addition to testimony regarding the subject’s occupational history and associated potential asbestos exposures, the questioning covered family occupational histories (parents and anyone cohabitating with the subject), hobbies that included use of products that might contain asbestos, residence in an area with potential environmental exposures, known abatement of asbestos in school, home renovations that might have used asbestos-containing materials, and any other potential sources of asbestos

³ The article was published in the January 2020 edition of the Journal of Occupational and Environmental Medicine. (Dkt. 274-1.)

exposure. (*Id.*) The 33 study subjects did not identify any workplace or household asbestos exposure apart from talcum powder. (*Id.* at 14; Dkt. 265-1 (“no known asbestos exposure other than to cosmetic talcum powder”).) Notably, the limitations of the Study and methodology employed are disclosed:

The case series presented should be understood in the context of its limitations. Data were obtained from medication records and transcripts of depositions, rather than structured, in-person interviews. However, the information solicited during the course of the patients' depositions were thorough, and included exhaustive questioning about alternative sources of asbestos exposure, including household exposure, exposures from external industrial sources, occupational exposure, and potential exposure from family members. While deposition testimony is by definition self-report, depositions were given under oath and the potential for recall bias noted would be presented whether patients completed a structured interview or were asked questions during sworn testimony. Furthermore, the utilization of medical records allowed the authors to corroborate important medical information and confirm the pathological diagnosis. (*Id.* at 14.)

The Study “provides evidence that mesothelioma cases once considered idiopathic may be attributable to asbestos-contaminated cosmetic talcum powder usage and that the elicitation of a history of such usage is imperative to obtaining a full exposure history in all patients presenting with mesothelioma.” (*Id.* at 16.) It is “the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users.” (*Id.* at 14.)

PROCEDURAL HISTORY

All served a subpoena to produce documents on Dr. Moline’s employer, Northwell Health, Inc. (“Northwell”). (Dkt. 168-1.) The subpoena sought various confidential and/or irrelevant documents pertaining to Dr. Moline. (*Id.*) Plaintiff filed a motion to quash the subpoena on September 3, 2020. (Dkt. 168.)

On September 11, 2020, Plaintiff's counsel's office sent an email to all Defendants' counsel regarding rescheduling the date of Dr. Moline's deposition pending the Court's ruling on Plaintiff's motion to quash. (Dkt. 179-4.) In his response, AII's counsel, Mr. Thackston, stated that "Northwell has confirmed that the Betty Bell case is one of the cases in Dr. Moline's study." (*Id.*) Plaintiff and his counsel were completely unaware that Northwell had produced any documents in this case.

Mr. Thackston had contacted Northwell directly and provided Northwell with a "HIPAA authorization," which authorized the disclosure of certain protected medical information.⁴ (Dkt. 179-4, 179-5, 179-6.) Upon receipt of the authorization, Northwell produced a single document (the "Northwell document"), a spreadsheet purportedly identifying the 33 human subjects of the Moline Study with all information except that relating to Mrs. Bell redacted. (Dkt. 179-5.) The document was not covered by the categories in the Authorization, nor was it responsive to any of the requests in AII's subpoena.

Plaintiff filed an Emergency Motion for Protective Order seeking to preclude discovery and inquiry into the identities of the human study subjects of the Moline Study, as well as a Motion to Seal its Motion for Protective Order. (Dkt. 179-182.) AII opposed Plaintiff's Motions. (Dkt. 197, 198.)

On September 25, 2020, Magistrate Judge Peake granted Plaintiff's motion for protective order in large part. (Dkt. 206, at 94:19-24, 96:6-12.) The Court held that the redacted Northwell document can be used in this case, but that it and the information therein regarding Mrs. Bell's identity as one of the 33 subjects in the Moline Study "is confidential and limited solely to this case." (*Id.*)

⁴ Plaintiff had provided a "HIPAA Compliant Authorization Form Pursuant to 45 FR 164-508" to Defendant earlier in this case to enable the parties to obtain the relevant medical records from Ms. Bell's health care providers.

at 94:19-24, 96:6-12.) The Court clarified that order may need to be reconsidered under a different standard as part of dispositive motions or at trial. (*Id.* at 95:3-7.) In addition, the Court granted the Parties' motions to seal. (*Id.* at 95:8-12 (regarding Dkt. 180 and 200).)

On December 23, 2020, Northwell filed a Motion to Intervene and Extend Protective Order, seeking to prevent Defendants' counsels from questioning Dr. Moline about any link between Mrs. Bell and the Study because forcing Dr. Moline to disclose the identity of a study subject would be contrary to the Federal Policy for the Protection of Human Subjects, bedrock IRB standards of privacy and confidentiality covering research subjects, the specific IRD approvals that Dr. Moline secured before writing and publishing the Article, well-established standard and universally-accepted norms in the medical research community related to the anonymity of research subjects, and relevant case law affirming privacy and confidentiality requirements for research subjects.⁵ (Dkt. 258, 265.) Northwell attached an affidavit from Dr. Moline, in which she explained the efforts she undertook to protect the confidentiality of the study subjects, as well as the approval process for the anonymized study. (Dkt. 265-1.) Northwell also filed a Motion to Seal its Motion to Intervene, Brief, and Dr. Moline's affidavit. (Dkt. 260.)

Because Plaintiff was required to make Dr. Moline available for deposition while Northwell's motion was pending, Plaintiff effectively withdrew Dr. Moline as an expert by not presenting her for deposition. (*See* Dkt. 309, at 3.) Plaintiff elected not to offer Dr. Moline for deposition because there was no resolution as to the proper scope of her questioning and because Plaintiff determined that he could prove his case with the remaining experts.

⁵ Plaintiff incorporates all arguments made by Northwell in its Motion to Intervene and accompanying Brief (Dkt. 264-265.)

On February 25, 2021, Magistrate Judge Peake denied Northwell's Motion to Intervene as mooted, untimely and without merit, but granted the related motions to seal and sealed the Order. (Dkt. 309.) Northwell filed an Objection (Dkt. 316), but the Court affirmed the Magistrate Judge's Order. (Dkt. 350.) On June 10, 2021, a redacted version of the Court's Order was signed and entered. (Dkt. 354.)

Shortly thereafter, the Court granted AII's motion for summary judgment. (Dkt. 361.) AII had moved for summary judgment based solely on successor liability, asserting that it is not a corporate successor to Neslemur, the entity that manufactured the Clubman that Mrs. Bell used. (Dkt. 288.) The remaining Defendants were dismissed, and Judgment was entered on August 25, 2021. (Dkt. 364, 365, 366.)

On September 29, 2021, thirty-five days later, AII filed the present Motion to Vacate the Protective Order. (Dkt. 368.) WCD filed a joinder in AII's motion on October 13, 2021. (Dkt. 373.) Defendants are requesting the Court vacate the Protective Order that protects the identification of Mrs. Bell as one of the human study subjects in the Moline Study from disclosure outside of this case.

LEGAL ARGUMENT AND AUTHORITY

I. RELEVANT LEGAL STANDARD

A. Modification of Protective Order

Defendants are seeking to modify or vacate the protective order entered orally by the Court on September 25, 2020, to the extent it precludes Defendants from using the Northwell document or disclosing confidential information regarding the identity of Mrs. Bell as one of the study subjects in the Moline Study outside of this case. (Dkt. 76:15-24). The standard for modifying a protective order is dependent upon whether the parties were required to demonstrate good cause for the

issuance of the order. *Factory Mut. Ins. Co. v. Insteel Indus.*, 212 F.R.D. 301, 303 (M.D.N.C. 2002) (citing *Longman v. Food Lion, Inc.*, 186 F.R.D. 331, 333 (M.D.N.C. 1999)). If good cause was shown, the party seeking to modify the order must show good cause. *Id.* (citing *Bayer AG v. Barr Lab.*, 162 F.R.D. 456, 463-64 (S.D.N.Y. 1995)). Here, Plaintiff moved for the protective order during discovery, All opposed, and the Court granted the motion in large part, necessarily finding that Plaintiff demonstrated good cause. *Longman v. Food Lion, Inc.*, 186 F.R.D. 331, 333 (M.D.N.C. 1999). Because Defendants are seeking to modify and vacate the order, they bear the burden of demonstrating good cause to justify doing so. *Id.* They have not done so.

B. Unsealing of Court Records

Defendants have requested the Court to modify and vacate the protective order entered in this case—they have filed a motion seeking to unseal any sealed court filings pursuant to Local Rule 5.4(e). However, the legal authority cited by Defendants, including the relevant legal standard, relates to the sealing of court filings, not the modification of a protective order. As a result, the legal argument set forth by Defendants is not applicable to their Motion. Indeed, Defendants assert that the Northwell document is a judicial record, to which the presumption of the public right of access attaches. (Dkt. 369, at 12.) *See Va. Dep't of State Police v. Wash. Post*, 386 F.3d 567 (4th Cir. 2004). However, the public right of access is not raised by the entry or modification of a protective order.

“The common law presumes a right to inspect and copy judicial records and documents.” *BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc.*, No. 1:10CV276, 2013 U.S. Dist. LEXIS 200199, at *3 (M.D.N.C. Mar. 29, 2013) (quoting *Stone v. Univ. of Md. Med. Sys. Corp.*, 855 F.2d 178, 180 (4th Cir. 1988)). For the right of access to apply to a document (including one subject to a protective order) to exist, the document must be a judicial record. *United States v. Appelbaum (In re United States)*, 707 F.3d 283, 290 (4th Cir. 2013). *Mr. Dee's Inc. v. Inmar, Inc.*, No.

1:19cv141, 2021 U.S. Dist. LEXIS 16137, at *6-7 (M.D.N.C. Jan. 28, 2021). AII asserts that “it is undisputed that the Northwell document is a judicial record.” But it is not “undisputed”—Plaintiff asserts the Northwell document is *not* a judicial record.

“[T]he mere filing of a document with a court does not render the document judicial.” *Hatch v. DeMayo*, No. 1:16cv925, 2020 U.S. Dist. LEXIS 194898, at *17-18 (M.D.N.C. Oct. 21, 2020) (quoting *Spear v. Ernst & Young (In re Policy Mgmt. Sys. Corp.)*, No. 94-2254, No. 94-2341, 1995 U.S. App. LEXIS 25900, at *13 (4th Cir. Sep. 13, 1995)); *United States v. Moussaoui*, 65 F. App'x 881, 889 (4th Cir. 2003) (observing some court-filed documents “may not qualify as ‘judicial records’ at all”). Documents filed with the court are “judicial records” if they play a role in the adjudicative process, or adjudicate substantive rights. *In re United States*, 707 F.3d at 291. “Documents filed to facilitate protective orders and other discovery motions do not qualify as judicial records.” *United States ex rel. Thomas v. Duke Univ.*, No. 1:17-CV-276, 2018 U.S. Dist. LEXIS 150001, at *9 (M.D.N.C. Sep. 4, 2018) (holding that a document filed to facilitate ruling on a protective order is not a “judicial record” triggering a First Amendment or common law right of public access)); *Kinetic Concepts, Inc. v. Convatec Inc.*, No. 1:08-CV-918, 2010 U.S. Dist. LEXIS (M.D.N.C. Apr. 2, 2010) (finding exhibits to motions to compel and for a protective order are not judicial records)). Likewise, documents filed in connection with a motion to seal are not judicial records. *Guessford v. Pa. Nat'l Mut. Cas. Ins. Co.*, No. 1:12-CV-260, 2014 U.S. Dist. LEXIS 196577 (M.D.N.C. Sept. 30, 2014).

AII argues that the Northwell document is a judicial record because it was attached to AII's Opposition to Northwell Health's Objections and Appeal (Dkt. 331, 331-17), and was the subject

of “numerous motions,” including Plaintiff’s Motion to Quash (Dkt. 168)⁶, Plaintiff’s Motion for Protective Order (Dkt. 179), All’s Responses in Opposition to Plaintiff’s Motion to Quash (Dkt.188) and Motion for Protective Order (Dkt. 197), Northwell’s Motion to Intervene (Dkt. 265), All’s Briefs in Opposition to Northwell’s Motion to Intervene (Dkt. 274) and Motion to Seal (Dkt. 275), Northwell’s Objections and Appeal (Dkt. 216) and All’s Response in Opposition to Northwell’s Motion to Seal Objections (Dkt. 330). All of these documents were filed to facilitate the protective order or in connection with a motion to seal; they concern the issue of whether or not the Northwell document (and information contained therein) is confidential and should be protected from disclosure. None of the filings played any role in adjudicating substantive rights. Court filings seeking to protect the confidentiality of a document cannot destroy confidentiality and create a public right to access a document where one did not exist. Thus, none of records cited by Defendants are judicial records subject to common right of access.

Because they are *not* judicial records, the sealing of the cited documents (as well as any others related to the identity of the study subjects) is subject to the “good cause” standard of Fed. R. Civ. P. 26(c). *BASF Agro B.V. Arnhem (NL), Wadenswil Branch v. Makhteshim Agan of N. Am., Inc.*, No. 1:10CV276, 2013 U.S. Dist. LEXIS 200199, at *2-3 (M.D.N.C. Mar. 29, 2013). The Court sealed the records, consistent with the protective order, which was entered after Plaintiff demonstrated good cause, and Defendants have not shown any reason to justify unsealing. *Fussman v. Novartis Pharm. Corp.*, No. 1:06CV149, 2010 U.S. Dist. LEXIS 144381, at *8-9 (M.D.N.C. Oct. 7, 2010); L.R. 5.4(e)(Court may modify orders sealing court records upon a motion by a party previously heard showing that sealing is no longer needed). The sealed documents

⁶ Plaintiff disputes that the Northwell document was the subject of his motion to quash the Northwell subpoena. At the time of filing, Plaintiff was unaware such a document even existed, and the subpoena did not seek documents identifying the subjects of the Moline Study.

played no role in the adjudication of Plaintiff's claims; they were not used in conjunction with a motion for summary judgment, motion *in limine* or other substantive motion. Because the documents have *not* become judicial records with a presumption of the public right to access, the legal standard to be applied ("good cause") has not changed. Defendants have offered no evidence or argument that the circumstances have changed such that good cause no longer exists. The documents should remain sealed.

Nevertheless, should Defendants' motion to vacate the protective order be considered as if it were a motion to unseal court records pursuant to L.R. 5.4(d), *and* if such court records are deemed to be judicial records despite being filed to facilitate a protective order and/or motion to seal, the common law presumption of access would attach to the documents.⁷ In that scenario, pursuant to Local Rule 5.4(e), Defendants must show that the sealing of the documents is no longer needed because the public's interest in access now outweighs competing interests. *In re Knight Publ'g Co.*, 743 F.2d 231, 235 (4th Cir. 1984). But, here, as previously determined, "the important confidentiality interests involved in human-subjects research, both on the part of the subject and the researcher" outweigh any interest of the public in disclosure. (Dkt. 360, at 2.)

II. THE COURT SHOULD DENY DEFENDANTS' MOTION TO VACATE THE PROTECTIVE ORDER.

The Court's entry of the protective order was predicated on Plaintiff's demonstration of good cause. Because Defendants are now seeking to modify or vacate the protective order, they must show good cause justifying the modifying or vacating of the protective order *Factory Mut. Ins. Co. v. Insteel Indus.*, 212 F.R.D. 301, 303 (M.D.N.C. 2002). Defendants have failed to do so. The same arguments that led the Court to grant the protective order continue to apply.

⁷ Plaintiff strongly disagrees with and opposes both hypothetical premises.

A. *Good Cause Exists for the Protective Order and the Sealing of Related Documents*

Plaintiff demonstrated good cause exists for a protective order pursuant to Rule 26(c) limiting discovery into the 33 human subjects of the Moline Study and prohibiting disclosure of confidential research and the identification of Mrs. Bell as one of the subjects outside of this case. (See Dkt. 179, 182; Dkt. 206.) Good cause continues to exist for the protective order prohibiting the disclosure of the identity of the human subjects, including Mrs. Bell, for the same reasons set forth in Plaintiff's Emergency Motion for Protective Order, incorporated herein. (See Dkt.179.) The identities of human subjects of medical research and studies are protected, confidential information. See, e.g., *Lampshire v. Procter & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982); *Doe v. Am. Red Cross Blood Servs., S.C. Region*, 125 F.R.D. 646 (D.S.C. 1989).

The need to protect the identity of the subjects of the Moline Study has been acknowledged by defense experts. Dr. Gregory Diette, M.D., while testifying on behalf of Johnson & Johnson, expressed concern if the identities of the 33 study subjects were disclosed publicly, particularly without the approval by the ethics board and an informed consent process. (Dkt. 179-7, at 118:10-119:16.) Likewise, Dr. Victor Roggli, Ms. Bell's diagnosing pathologist, expert witness for defendants, and author of multiple published case studies on human subjects, stated:

I also have objection to it because in -- personally, because in the 25 years that I've been testifying as an expert in federal and state courts these requests go far beyond anything that have been requested of myself or my colleagues that I'm aware of, and I don't think that they are appropriate investigation into scientific merit or arguments that are made in the scientific literature...

(Dkt. 179-8, at 42:9-45:21.)

The disclosure of the identity of human subjects would have a chilling effect on further research. Good cause for a protective order prohibiting disclosure of the identity of any study

subjects (including Ms. Bell) outside of the case, and sealing of motions containing the same information, persists and is persuasive.

B. Defendants Have Not Met Their Burden to Prove Good Cause Exists to Vacate the Protective Order.

Defendants fail to demonstrate that good cause exists to vacate the protective order.⁸

1) Disclosure of the Protected Information Would Not Rectify an Injustice.

Defendants argue that disclosure of the protected information would rectify an injustice because it would prevent Dr. Moline and others from misrepresenting that the Study shows that cosmetic talc causes mesothelioma to. Defendants definitively assert that “we know” that the representation in the Moline Study that none of the 33 subjects had alternative exposures to asbestos “is false, at least in Ms. Bell’s case, and probably others.” (Dkt. 369, at 14.) “We” know no such thing. Indeed, ***there is no actual evidence that Mrs. Bell was exposed to any alternative source of asbestos*** or that Dr. Moline has made any misrepresentation regarding Mrs. Bell.

(a) Betty Bell Has No Known Alternate Exposure

Defendants’ entire motion is premised on its unfounded belief that Dr. Moline improperly included Mrs. Bell as one of the 33 human subjects in the Study because she and Plaintiff filed unsuccessful workers’ compensation claims. Defendants repeatedly conflate an allegation of potential exposure with evidence of a known alternate exposure. There is no evidence that Mrs. Bell was *actually* exposed to asbestos at her jobsites. Indeed, the fact that Plaintiff and Mrs. Bell filed workers’ compensation claims against *two* employers demonstrates an uncertainty and ambiguity regarding Mrs. Bell’s potential exposure and causation since only “the employer in

⁸ Defendants apply factors related to a balancing test relevant to the sealing of documents. Nevertheless, Plaintiff considers the factors discussed by Defendants in the context of Defendant’s burden to demonstrate good cause.

whose employment the employee was last injuriously exposed to the hazards of such disease, [and insurance carrier] shall be liable” in covered mesothelioma cases since under North Carolina’s Workers’ Compensation Act. N.C. Gen. Stat. § 97-57. If Plaintiff and Mrs. Bell had evidence that Mrs. Bell was exposed to asbestos at Pillowtex during her employment, Pillowtex would have been liable as the employer during the last injurious exposure, and there would have been no reason to also assert a claim against Celanese.

Defendants conveniently ignore that reams of discovery and the sworn deposition testimony of multiple fact witnesses, including Mrs. Bell, have failed to provide any evidence that Mrs. Bell was exposed to asbestos while working at Pillowtex or Celanese. Nevertheless, Defendants continue to baselessly attack Dr. Moline for including Mrs. Bell in the Study despite her alternate exposure, *but there is no known alternate exposure*. There is no injustice to rectify.

(b) Defendants Are Not Prevented From Cross-Examining Dr. Moline

Maintaining the anonymity of Dr. Moline’s study subjects would not prevent Defendants from effectively cross-examining Dr. Moline. Defendants may question Dr. Moline regarding the limitations or reliability of the methodology utilized in the Study. Moreover, Defendants may effectively cross-examine Dr. Moline on the exact issue they have with the Moline Study without disclosing the Mrs. Bell’s identity as demonstrated by WCD’s counsel at the recent *McNeal* trial:

Q Okay. And after you published the paper and testified in Congress about the paper, did you come to learn that some of the information regarding one or more of the people in your study was incorrect as published?

A There was a question about one particular individual that I was presented with information about, but I -- based on the information that I had, there was -- it wasn't determined that they had the -- any additional exposure. I'm not sure of any others.

Q Did you publish an errata with regard to your paper after you found out that this one plaintiff that was provided to you had other alleged exposures?

A As I said just a minute ago, there was an allegation or there was a -- a comment, but it was shown to be without evidence, so I did not publish an errata based on that one individual.

Exhibit 1, Trial Testimony in *McNeal v. AutoZone, et al.*, April 1, 2021, Superior Court of the State of California for the County of Los Angeles, No. BC698965, at 1666:26-1667:27. Cross-examining Dr. Moline in this way permits Defendants to question Dr. Moline regarding the reliability of the Study without devolving into inevitable mini-trials regarding Mrs. Bell's possible exposures in every case in which Dr. Moline is retained or an expert relies upon her study.

Defendants are requesting the Court vacate the protective order so that they may attempt to discredit Dr. Moline and the Study despite having no legitimate basis for doing so. Defendants ignore all evidence (or lack thereof) that indicates Mrs. Bell had no known alternate exposures, choosing to focus solely on the unsuccessful and unsupported workers' compensation claims.

2) Disclosure of the Protected Information Contributes Nothing to the Public Understanding.

Defendants argue that the accuracy and reliability of Dr. Moline's claims are a matter of public interest. While Plaintiff does not dispute that the accuracy and reliability of scientific studies is a matter of public interest, Defendants have no genuine basis for disputing the accuracy and reliability of the Moline Study. Defendants should not be permitted to disclose protected, confidential information regarding the human subjects of peer-reviewed studies, certainly when based on nothing but their own baseless suspicions. The evaluation of the reliability and accuracy of a published study—particularly one that has been peer reviewed—does not require the deanonymization of the human subjects and the disclosure of the underlying data. The public interest is not served by disclosing the identity of human subjects of research studies.

Moreover, Defendants lament that litigation and related costs have forced some cosmetic sellers, including AII, to withdraw their asbestos-containing cosmetic talcum powder products from the market. Defendants are disingenuously implying that AII was forced to switch to cornstarch because of the Moline Study and her alleged misrepresentation regarding one of her 33 subjects. But AII discontinued its sale of talcum powder in 2017, before the Moline Study was published. (Dkt. 369-6, at 74:25-75:13.) The Moline Study provides further evidence that cosmetic talc causes mesothelioma, but is only one piece of the story.

3) Confidentiality Interests Outweigh the Public's Interest in Access

Defendants assert that no counterveiling interests outweigh the public interest because the Study is not “human subject research,” the data is not HIPAA protected, and Mrs. Bell waived any general claim to privacy. For reasons set forth below and in Plaintiff's Emergency Motion for Protective Order (Dkt. 179) and Reply (Dkt. 199), these arguments do not hold water.

First, Defendants assert that the Moline Study is not “human study research” because Mrs. Bell has passed away, but Mrs. Bell was a living individual when the information used in the Study was obtained from her. 45 C.F.R. § 46.102(e). Moreover, Mrs. Bell was only one of 33 study subjects that were living when the information used by Dr. Moline was obtained.

Second, Dr. Moline was not required to obtain informed consent because she anonymized the study subjects and secured approval from Northwell's IRB, which determined the Study had adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data. (Dkt. 265-1, Moline Affidavit, at 2.)

Third, Defendants argue that because no statute protects research data from compelled disclosure, it cannot be protected. The disclosure of the identity of the human subjects of the Moline Study has not been compelled. Moreover, Rule 26(c) explicitly permits a court to issue an

order requiring that confidential research not be revealed or be revealed only in a specified way. Fed. R. Civ. P. 26(c)(1)(g).

Fourth, Plaintiff does not assert that the Northwell document is protected by HIPAA—rather that the HIPAA authorization was improperly used to obtain the Northwell document. Mr. Thackston used the Authorization to persuade Northwell to produce a single file—the key to the identities of the Moline Study human subjects—which was neither responsive to AII’s subpoena nor within the categories of documents covered by the HIPAA authorization.

4) Other Interested Parties Have Not Sought Public Disclosure of the Northwell Document or the Information Contained Therein.

Defendants assert that the fact that no interested party has moved to unseal the information is irrelevant because the protective order prohibits Defendants from publicizing that the Northwell document shows that Mrs. Bell was one of the 33 human subjects in the Moline Study and because the case has not been subject to substantial media attention. But there is a motion to seal describing every sealed document, including why it is sealed. The information necessary for an interested non-party to determine whether to seek to unseal the document(s) is available. Moreover, this factor is not limited in application to cases that dominate the headlines.

Other parties may not have sought to unseal because they recognize that the confidentiality involved in human-subjects research outweigh any interest of the public in disclosure. They may recognize that their own experts have published and/or relied upon similar case series studies, and don’t want to open the door to the deanonymization of study subjects. Or they may respect Dr. Moline, not believing Defendants’ baseless and insulting accusations of fraud and misrepresentation. WCD has filed no pleadings seeking to unseal the documents, having only joined in AII’s latest motion to vacate the protective order, despite having full knowledge of the information and facing Dr. Moline at trial in the *McNeal* case in April 2021.

III. THE COURT SHOULD NOT UNSEAL ANY COURT RECORDS.

Defendants did not request the Court to unseal any court records. Even if they had moved to unseal, they have not and could not demonstrate good cause no longer exists for sealing the documents or that the public interest in access outweighs the competing interests.

A. The Sealed Records Are Not Judicial Records And Defendants Have Not Shown Good Cause No Longer Exists for Sealing.

As explained *supra*, the sealed records in this case are not judicial records, and therefore and not subject to the presumption of the right of public access. Because the sealed records were attempts to facilitate a protective order or to seal, the records are not judicial records. No public right of access applies.

The Court's previous determination that good cause exists to seal records regarding the identity of the human subjects of the Moline Study should not be disturbed. As set forth in II.A *supra*, Defendants have failed to demonstrate good cause exists for removing the confidentiality protections.

B. Even if the Sealed Records Are Judicial Records, the Public Interest in Access Is Heavily Outweighed By Confidentiality Interests Involved in Human-Subject Research.

If the sealed records are "judicial records" to which the public right of access applies (which Plaintiff strongly disputes), Defendants have failed to meet its burden to unseal. As discussed in detail in II.B. *supra*, Defendants have not demonstrated that the public's interest in access to the identity of a human subject of a published, peer-reviewed Study outweighs the interest in protecting the confidentiality of the identities of human research subject, particularly in the present case where disclosure of the identity of one of the human subjects will serve no legitimate purpose. Contrary to Defendants' groundless assertions, denied workers' compensation claims – with no actual evidence of exposure to asbestos – does not make Dr. Moline's representation that

Mrs. Bell had no known alternate exposures false. Indeed, Defendants' repeated assertion that the Moline Study is "deeply flawed" and that she gives "false" testimony is simply not true. Disclosure of the identity of Mrs. Bell as a human subject ultimately would have little to no effect on talc litigation – any issues regarding the reliability and accuracy of the Study can be effectively probed on cross-examination.

CONCLUSION

WHEREFORE, Plaintiff respectfully prays that AII's Motion to Vacate the Protective Order and WCD's Joinder therein be denied and that the Protective Order prohibiting disclosure of the identity of any human subject of Dr. Moline's peer-reviewed Study remain in force. Regardless of whether Defendants' motion is considered a motion to vacate the protective order or a motion to unseal records, Defendants have failed to meet their burden. Defendants have not demonstrated good cause for modifying or vacating the protective order or for unsealing the records. Further, the confidentiality interests involved in human-subjects research still outweigh any interest of the public in disclosure.

Dated: October 20, 2021.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 20, 2021, the foregoing was filed via CM/ECF filing system, which will send notification of this filing and an electronic copy of same to all counsel of record in the above-referenced matter.

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